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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,480	05/19/2000	Gregory A Kopia	CRD-850	1106

7590 01/26/2004

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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	19

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/575,480	KOPIA ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment/RCE

This is a response to the amendment/RCE dated October 24, 2003. Claims 1 and 3-9 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, and 6-9 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Pinchuk et al. in US Patent No. 6,545,097.

Regarding claim 1, Pinchuk et al. disclose a method for treating restenosis having an intravascular infusion or delivery by release from a surface of a stent a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth having rapamycin or an analogue thereof and an anti-inflammatory, in therapeutic dosage amounts, as recited in column 3, lines 12-18, column 7, lines 1-5, column 11, lines 35-40 and column 13, lines 1-30, etc. Pinchuk et al. state, "In addition, combinations of the above therapeutic agents can be used." Thus, there is clear disclosure to combine agents for their

known properties. Thus, when treating restenosis one would combine the known anti-proliferative rapamycin or analogues thereof with an anti-inflammatory.

Regarding claim 3, Pinchuk et al. disclose that as applied to claim 1, as well as, an anti-inflammatory agent that is dexamethasone and an anti-proliferative that is from the group of rapamycin, taxol, or vincristine, as recited in column 7, lines 1-5 and column 13, lines 1-30, for example.

Regarding claim 4, Pinchuk et al. disclose that as applied to claim 1, as well as a combination that further includes a growth factor or cytokine signal transduction inhibitor, as recited in column 7 and column 13, lines 25-30.

Regarding claim 6, Pinchuk et al. disclose that as applied to claim 1, as well as a tyrosine kinase inhibitor, as recited in column 7.

Regarding claim 7, Pinchuk et al. disclose that as applied to claim 6, as well as a tyrosine kinase inhibitor that is tyrphostin and an anti-proliferative that is taken from the group of rapamycin, taxol, vincristine, as state in column 7, (with emphasis on lines 5-10 and 30-50) and column 13.

Regarding claim 8, Pinchuk et al. disclose that as applied to claim 1, as well as a combination of agents that further include an inhibitor of extracellular matrix synthesis, as recited in column 9, lines 40-60.

Regarding claim 9, Pinchuk et al. disclose that as applied to claim 8, as well as an inhibitor of extracellular matrix synthesis that is halofuginone and the anti-proliferative is taken from the group of rapamycin, taxol or vincristine, as recited in column 13, lines 1-30.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. in US Patent No. 6,545,097.

Regarding claim 5, Pinchuk et al. disclose that as applied to claim 4. Although not explicitly recited a cytokine signal transduction inhibitor that is a ras inhibitor, R115777 is within the scope of the invention and would be obvious to one with ordinary skill in the art.

5. Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Morris et al. in US Patent No. 5,516,781.

Regarding claim 1, Ragheb et al. disclose a process for the treatment of restenosis via intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth and an anti-inflammatory for inhibiting smooth muscle growth in therapeutic dosage amounts, as recited in column 2, lines 40-67, column 3, lines 54-67, column 4, column 7, lines 62-67, column 8, and column 9. However, Ragheb et al. do not explicitly recite an anti-proliferative that is rapamycin or analogue thereof. On the other hand, Morris et al. teach of the properties of rapamycin as an anti-proliferative and it is a known property of the drug. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Ragheb et al. to include rapamycin for the purpose of its superior qualities as an anti-proliferative.

Regarding claim 3, Ragheb et al. as modified disclose that as applied to claim 1, as well as, an anti-inflammatory agent that is dexamethasone and an anti-proliferative that is taxol, as recited in column 9, lines 45-55.

Regarding claim 4, Ragheb et al. as modified disclose that as applied to claim 1, as well as, a combination of a growth factor and an anti-proliferative, as recited in column 9, lines 50-60 and column 21, lines 45-55, and column 4, lines 55-60, wherein any combination of bioactive materials can be employed.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Morris et al. in US Patent No. 5,516,781 and further in view of End.

Ragheb et al. as modified by Morris et al. disclose the invention as applied to claims 1. However, Ragheb et al. do not explicitly recite R11577. On the other hand, End teaches the ras inhibitor, R11577. Therefore, it would be obvious to one with ordinary skill in the art modify the invention of Ragheb et al. to include R115777 as a signal transduction inhibitor for the purpose of increasing antiproliferation.

7. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Morris et al. in US Patent No. 5,516,781 and further in view of Levitzki et al. in US Patent No. 5,932,580.

Ragheb et al. as modified by Morris et al. disclose the invention as applied to claim 1. However, Ragheb et al. do not explicitly recite tyrphostin as a tyrosine inhibitor. However, Levitzki et al. teach of tyrphostin, as recited in column 5, lines 35-67, column 6, and column 8. Therefore, since implantation is a method of administration as recited in column 8, line 67, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Ragheb et al. to include a the tyrosine inhibitor of tyrphostin to suppress SMC.

8. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. in US Patent No. 6,299,604 in view of Morris et al. in US Patent No. 5,516,781 and further in view of Nagler et al. in US Patent No. 6,159,488.

Ragheb et al. as modified by Morris et al. disclose the invention as applied to claims 1 and 3-4. However, Ragheb et al. do not explicitly recite halofuginone as an inhibitor of extracellular matrix. On the other hand, Nagler et al. teach a stent coated with halofuginone, as recited in column 9 and column 10. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Ragheb et al. to include halofuginone for the purpose of inhibiting SMC proliferation.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 3-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 25 of copending Application No. 09/850,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for identical subject matter. In some aspects some limitations are broader while others are more specific.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700